K131830
Page 1 of 3

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Edan Instruments, Inc.

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Contact Person: Cherry Sun

SEP 17 2013

Prepare date: June 13th, 2013

2. Device name and classification:

Device Name:

Digital Ultrasonic Diagnostic Imaging System, Model DUS 60

Classification Name:

892.1560 System, Imaging, Pulsed echo, Ultrasonic

Product code: IYO

892.1570 Transducer, Ultrasonic, Diagnostic

Product code: ITX

Regulatory Class: Class II

3. Predicate Device:

M5 Diagnostic Ultrasound System K102991

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

DC-6 Diagnostic Ultrasound System K072164

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

U50 Diagnostic Ultrasound System. K123249
Manufacturer: SHENZHEN EDAN INSTRUMENTS CO., LTD

4. Device Description:

The DUS 60 is a portable Diagnostic Ultrasound System, which applies advanced technologies such as Phased Inversion Harmonic Compound Imaging (eHCI), Double-Beam-Forming (D Beam), Speckle Resistance Imaging(eSRI), scan receiving aperture(SRA) and Spatial Compounding Imaging, etc. Various image parameter adjustments, 12.1 inch LCD and diverse probes are configured to provide clear and stable images. It is intended for diagnostic ultrasound imaging analysis in hospitals and clinics.

It is designed to produce ultrasound waves into body tissue and present the returned echo information on the monitor; which can be displayed in the following modes: B/2B/4B-Mode, M-Mode, B+M Mode or PW Mode. Supported probe types include convex, linear, micro-convex, endocavity (transvaginal, endorectal) probes. The device can detect the probe automatically.

The system consists of 7 major functional blocks, including a main unit, a display subsystem, a transducer and transceiver subsystem, digital beamformer, keyboard and power subsystem.

5. Intended Use:

The diagnostic ultrasound system (DUS 60) is applicable for ultrasound evaluation in hospitals and clinics. It is intended for use in Abdominal; obstetric, gynecology, pediatrics; small parts; urology, peripheral vascular, musculoskeletal (conventional and superficial), and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.

6. Effectiveness and Safety Considerations:

Clinical test:

Clinical testing is not required.

Non-clinical test:

The following safety standards are conducted on the subject device:
(1) IEC 60601-1 Electrical Safety
(2) IEC 60601-1-2 Electromagnetic Compatibility
(3) IEC 60601-2-37 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
(4) Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.
(5) ISO 10993-1, ISO 10993-5 and ISO 10993-10 Biological evaluation of medical devices

7.Comparison to the predicate device

The subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate devices. The differences between the subject

device and predicate devices do not affect the basic design principle, usage, effectiveness and safety of the subject device. And they don't affect the former's effectiveness and safety.

The subject device has the same needle-guide bracket material, property, and sterilization methods as those of the predicate device U50, therefore, the needle-guide bracket will not cause any safety and effectiveness issues.

8. Substantially Equivalent Determination

Verification and validation testing was conducted on the DUS 60 Digital Ultrasonic Diagnostic Imaging System. This premarket notification submission demonstrates that DUS 60 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 17, 2013

Edan Instruments, Inc.
% Ms. Cherry Sun
Certification Engineer
3/F – B, Nanshan Medical Equipments Park
Nanhai Road 1019#, Shekou,
Nanshan Shenzhen, 518067
CHINA

Re: K131830
Trade/Device Name: Digital Ultrasonic Diagnostic Imaging System, Model DUS 60
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: June 7, 2013
Received: June 20, 2013

Dear Ms. Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the DUS 60 Digital Ultrasonic Diagnostic Imaging System, as described in your premarket notification:

Transducer Model Number

C361-2	C363-2	C341-2
L741-2	L743-2	L761-2
C611-2	E741-2	E611-2

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K131830

Device Name: Digital Ultrasonic Diagnostic Imaging System, Model DUS 60

Intended Use:

The diagnostic ultrasound system (DUS 60) is applicable for ultrasound evaluation in hospitals and clinics. It is intended for use in Abdominal; obstetric, gynecology, pediatrics; small parts; urology, peripheral vascular, musculoskeletal (conventional and superficial), and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.

Prescription Use ___X___ Or Over the Counter Use _____.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K131830

Diagnostic Ultrasound Indications for Use Form

DUS 60 Digital Ultrasonic Diagnostic Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N			N	Note 1,2
	Abdominal	N	N	N			N	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N			N	Note 1,2
	Small Organ (Specify) *	N	N	N			N	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N			N	Note 1,2
	Trans-vaginal	N	N	N			N	Note 1,2
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1,2
	Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1,2
	Intravascular							
	Other (Specify) **	N	N	N			N	Note 1,2
Cardiac	Cardiac	N	N	N			N	Note 1,2
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N			N	Note 1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M, B+PW

* Small Organ includes thyroid

** Other use includes Urology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging. This feature does not use contrast agent.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C361-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N			N	Note 1,2
	Abdominal	N	N	N			N	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **	N	N	N			N	Note 1,2
Cardiac	Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M, B+PW

* Small Organ includes thyroid

** Other use includes Urology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging. This feature does not use contrast agent

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C363-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N			N	Note 1,2
	Abdominal	N	N	N			N	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **	N	N	N			N	Note 1,2
Cardiac	Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M, B+PW

* Small Organ includes thyroid

** Other use includes Urology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C341-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N			N	Note 1,2
	Abdominal	N	N	N			N	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **	N	N	N			N	Note 1,2
Cardiac	Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M, B+PW

* Small Organ includes thyroid

** Other use includes Urology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with L741-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	N	N	N			N	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1,2
	Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1,2
	Intravascular							
	Other (Specify) **							
Cardiac	Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N			N	Note 1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA: E = added under this appendix

Additional comments: Combined mode: B+M, B+PW

* Small Organ includes thyroid

** Other use includes Urology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with L743-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	N	N	N			N	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1,2
	Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1,2
	Intravascular							
	Other (Specify) **							
Cardiac	Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N			N	Note 1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M, B+PW

* Small Organ includes thyroid

** Other use includes Urology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with L761-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	N	N	N			N	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1,2
	Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1,2
	Intravascular							
	Other (Specify) **							
Cardiac	Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N			N	Note 1,2
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M, B+PW

* Small Organ includes thyroid

** Other use includes Urology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C611-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N			N	Note 1,2
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Cardiac	N	N	N			N	Note 1,2
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M, B+PW

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** Other use includes Urology

Note 1: Biopsy Guidance

Note 2: Harmonic Imaging, This feature does not use contrast agent

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with E741-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N			N	Note 1,2
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

DUS 60 with E611-2 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N			N	Note 1,2
	Trans-vaginal	N	N	N			N	Note 1,2
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)